510(k) Summary

DEC 17 2013

Manufacturer:	U & I Corporation 20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, Korea, 480-859
Sponsor:	U & I Corporation 20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, Korea, 480-859
Sponsor Contact:	Young-Geun, Kim, Regulatory Affairs Assistant +82 31 852 0102 (ext.619) ygkim@youic.com
Date Prepared:	Dec 17, 2013
Device Name:	Trade Name: Perfix™ Iliac Screw System
Classification Name:	Spinal Fixation System, per 21 CFR 888.3050 and 888.3070
Common Name:	Spinal Fixation System
Product Code:	MNH, MNI, KWP
Predicate Devices:	Synergy™ Spinal System – Synergy VLS Screws (K011437) OPTIMA™ Spinal System (K024096) Global Spinal Fixation System™ (K001668)

Description of Device:

Perfix™ Iliac Screw System consists of a variety of shapes and size of iliac screws, iliac connectors, iliac screw cap and set screw. All implant components are made from a titanium alloy (Ti-6Al-4V ELI) in accordance with ASTM F136. Perfix™ Iliac Screw System is intended to provide spinal stability related to the lumbosacral fixation or spinopelvic fixation. Fixation is provided by iliac screws inserted into the vertebral body of the lumbar spine and sacrum regions using a posterior approach.

Intended Use:

The Perfix™ Spinal System is a posterior, noncervical pedicle fixation system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion by autogenous bone graft in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar and sacral spine:

- Spondylolisthesis (Grade 3 and 4)
- Degenerative spondylolisthesis with objective evidence of neurological impairment
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Spinal deformities (Scoliosis, Kyphosis, Lordosis)
- Pelvic obliquity
- Spinal tumor
- Pseudarthrosis
- Failed previous fusion

The Perfix™ Iliac Screw System includes the following four components; iliac screw, iliac connector, iliac cap, and a set screw. These components are only to be used in conjunction with the Perfix™ Spinal System's 6.0mm diameter rods.

Substantial Equivalence:

The Perfix™ Iliac Screw System is substantially equivalent to Synergy™ Spinal System – Synergy VLS Screws (K011437), OPTIMA™ Spinal System (K024096) and Global Spinal Fixation System™ (K001668) in design, material, mechanical performance, function and intended use.

The mechanical performance of Perfix™ Iliac Screw System met the acceptance criteria which have been established from the predicate devices.

1. Comparison Technological Characteristics

The predicate and proposed devices have the similar intended use and basic fundamental scientific technology and share the following similarities;

- The similar indications for use
- Similar design features
- Incorporate the same or similar materials
- The equivalent mechanical performance

2. Performance Testing

The Perfix™ Iliac Screw System was tested in a non clinical setting (bench testing) to assess that to know new safety and efficiency issues were raised with this device. The testing met all acceptance criteria and verifies that performance of the Perfix™ Iliac Screw System is substantially equivalent to the predicate devices.

The following tests were performed:

1) Construct Test (ASTM F1717)
   (1) Static compression bending test
   (2) Static torsion test
   (3) Dynamic compression bending test

3. Conclusion

The data and information provided in this submission support the conclusion that the Perfix™ Iliac Screw System is substantially equivalent to its predicate devices with respect to indications for use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 17, 2013

U & I Corporation
Mr. Young-Geun Kim
Regulatory Affairs Assistant
20, Sandan-ro, 76beon-gil (Rd)
Uijeongbu-si, Gyeonggi-do
Republic of Korea 480-859

Re: K132218
Trade/Device Name: Perfix™ Iliac Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI, KWP
Dated: November 14, 2013
Received: November 15, 2013

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K132218

Device Name: Perfix™ Iliac Screw System

Indications for Use:

The Perfix™ Spinal System is a posterior, noncervical pedicle fixation system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion by autogenous bone graft in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar and sacral spine:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Zane W. Wyatt -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K132218